



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/534,985

10/23/2006

Andreas M. Zeiher

05552.1459

1864

22852

7590

12/28/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,985	Applicant(s) ZEIHER ET AL.	
	Examiner LISA V. COOK	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/16/05 6/10/05 8/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group III (claims 20, 21, and 23) in the reply filed on 7/16/09 is acknowledged. Applicant argues that Garlich et al. do not teach sCDL40 in the diagnosis and/or prognosis of acute coronary diseases. This argument was carefully considered but not found persuasive because Garlich et al. taught that elevated sCDL40 was found in patients with myocardial infarction and angina. See figure 2 and page 1026, for example. The traversal is on the ground(s) that it would not be a serious burden for the examiner to carry out a search for the full scope of the invention. This is not found persuasive because the diverse method claims require the detection of independent and distinct method steps, correlation, and reagents. Each method step/correlation requires a separate search and consideration, thus imposing a search burden for the examiner.
2. Claims 1-19 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
3. The requirement is still deemed proper and is therefore made FINAL.
4. Currently claims 20, 21, and 23 are under consideration

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form PTO-1449 lists the references, they have not been considered.
6. The information disclosure statement filed 5/16/05 has been considered as to the merits before First Action.
7. The information disclosure statement filed 6/10/05 has been considered as to the merits before First Action.
8. The information disclosure statement filed 8/21/06 has been considered as to the merits before First Action.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1641

I. Claims 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayes-Genis et al. (The New England Journal of Medicine, Vol.345, No.14, October 4, 2001, pages 1022-1029).

Bayes-Genis et al. disclose methods of measuring PAPP-A in acute coronary syndromes. See page 1026 and figure 2. PAPP-A was found to be a marker for acute coronary syndrome. See entire reference.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

II. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bayes-Genis et al. (The New England Journal of Medicine, Vol.345, No.14, October 4, 2001, pages 1022-1029) in view of Corsini et al. (Pharmacology & Therapeutics, Vol.84, 1999, pages 413-428).

Please see Bayes-Genis et al. as set forth above.

Bayes-Genis et al. differ from the instant invention in not specifically teaching the administration of statins as a therapeutic vascular agent to a patient.

However, Corsini et al. teach procedures for administering statins to inhibit 3-hydroxy-3methyl-glutaryl coenzyme A. See abstract and Table 2. Statins can ameliorate vascular atherosclerosis and reduce cardiovascular-related morbidity and mortality in patients with or without coronary artery disease (CAD) symptoms. See page 414 -1st column, Introduction.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to treat the detected vascular patients of Bayes-Genis et al. with the statin drugs of Corsini et al. because Corsini et al. taught that Statins can ameliorate vascular atherosclerosis and reduce cardiovascular-related morbidity and mortality in patients with or without coronary artery disease (CAD) symptoms. See page 414 -1st column, Introduction.

11. For reasons aforementioned and already of record, no claims are allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Patent Examiner
Art Unit: 1641
Remsen
571-272-0816
12/21/09

/Lisa V. Cook/
Primary Examiner, Art Unit 1641

Art Unit: 1641